

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RLL-298WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IB 03/04873	International filing date (day/month/year) 31.10.2003	Priority date (day/month/year) 31.10.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/00		
Applicant RANBAXY LABORATORIES LIMITED		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application
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Date of submission of the demand 20.05.2004	Date of completion of this report 16.12.2004
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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB 03/04873

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-6 as originally filed

Claims, Numbers

1-21 as originally filed

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB 03/04873

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-21
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB 03/04873

Re Item V

1. The relevant prior art documents are referred to as D1 to D8 as in the order of appearance in the International Search Report (ISR).

2. Citations and explanations supporting the statement with regard to novelty (N), inventive step (IS) and industrial applicability (IA) (Article 33(1) PCT):

(N) The subject-matter of claims 1-21 is not novel as anticipated by the prior art (Article 33(2) PCT).

D1 discloses an amorphous form of potassium losartan and pharmaceutical compositions containing it. This takes away the novelty of present independent claims 1 and 4.

D2 to D4 disclose crystallization of potassium losartan (form I). First, the potassium salt is synthesized: the free acid form is treated with KOH and concentrated under vacuum prior to crystallization; concentration under vacuum of the reaction mixture must render an amorphous form of the potassium salt; thus an amorphous form is implicitly disclosed in D2 to D4. This takes away the novelty of present independent claims 1 and 4, as well as independent claim 7.

The same reasoning applies in view of D5 to D7, because the step of concentration of a solution or reaction mixture of the potassium salt under vacuum prior to crystallization implies the obtention of an amorphous form as an intermediate form. Thus, the amorphous form is implicitly anticipated. This takes away the novelty of present independent claims 1 and 4, as well as independent claim 7.

The mere spectroscopic characterization of a product or material which has been previously (explicitly or implicitly) disclosed does not establish novelty.

Furthermore, the parametric definition by reference to the figures in claims 2, 3, 5, 6, 20 and 21 is not allowable, because it results in lack of clarity (Art. 6 PCT).

(IS) The subject-matter of claims 1-21 is not considered to involve an inventive step (Article 33(3) PCT) (see above).

Further, the following consideration is brought to the applicant's attention:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB 03/04873

Selecting spray-drying or freeze-drying instead of vacuum concentration for obtention of the amorphous form would be an obvious alternative for the skilled person (see e.g. D8). No inventive step can be acknowledged for such subject-matter.

- (IA) The subject-matter of claims 1-21 is considered to be industrially applicable (Article 33(4) PCT. The possibility of industrial application is beyond any doubt.